STEALTH
THERAPEUTICS INC.

5.0 510(k) Summary

This summary is provided to support the 510(k) notification for the Invisiport™ manufactured for Stealth Therapeutics, Inc.

Company Name:	Stealth Therapeutics, Inc.
Address:	5520 Nobel Drive, Suite 150 Fitchburg, Wisconsin 53711
Phone:	(608) 577-4484
Date Summary Prepared:	February 8, 2011
Trade Name:	Invisiport™
Common Name:	Implantable Infusion Port
Classification Name:	Subcutaneous, Implanted, Intravascular Infusion Port and Catheter 21 CFR 880.5965, Product Code LJT
Predicate Devices:	K043178, Rhapsody Access Port manufactured by GrantAdler Corporation K060812, PowerPort™ Implantable Titanium Port manufactured by C.R. Bard, Inc. K060036, PORT-A-CATH manufactured by Smiths Medical K934518, PeriPort manufactured by Strato Medical Corp.

5.1 Product Description

The Invisiport™ consists of an injection port made from material evaluated for biocompatibility. The Invisiport has a self-sealing silicone septum. An open ended radiopaque catheter is pre-attached to the port. The silicone septum covers a reservoir that can be accessed with a non-coring Huber type needle. Power injection of contrast for imaging examinations can be performed when the port is accessed with a power-injectable Huber needle or infusion set.

5.2 Intended Use of the Device

The intended use of the Invisiport is the same as predicate devices:

> The Invisiport™ is indicated for any patient requiring repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, or the

sampling of blood, or for power injection of contrast media when used with a power-injectable Huber needle or infusion set.

5.3 Summary of Technological Characteristics

The following table provides a side-by-side comparison the Invisiport™ to the predicate devices being used to support this notification.

Table 5.3-1: Substantial Equivalence Technical Characteristics

Feature	**Invisiport™ (Under Review)**	**PeriPort** K934518	**GrantAdler Rhapsody Access Port** K043178, K082126	**Bard Power Port** K060812	**Smiths Medical PORT-A-CATH** K060036	**Comment**
Indications for Use	The *Invisiport™* is indicated for any patient requiring repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, or the sampling of blood, or for power injection of contrast when used with a power-injectable Huber needle or infusion set.	The PeriPort is a totally implantable drug delivery system designed to give repeated access to the venous system for infusions, nutritional solutions, medications, fluids, and for the sampling of venous blood.	The GrantAdler Rhapsody Access Port and Catheter is indicated for any patient requiring reliable repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products or the sampling of blood.	The PowerPort implanted port is indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with the PowerLoc Safety Infusion Set, the PowerPort device is indicated for power injection of contrast media. For power injection of contrast media, the maximum recommended infusion rate is 5 ml/s.	PORT-A-CATH –Systems with Dual Layer Catheter are indicated when patient therapy requires repeated vascular access for injection or infusion therapy and/or venous blood sampling.	The indication for use of the Invisiport is the same as the predicate devices, including power injection compatibility. The 5 ml/sec power injection of contrast media limit is the same as the Bard Power Port.
Port Access	Hospital/clinic licensed health care provider	Hospital/clinic licensed health care provider	Hospital/clinic licensed health care provider	Hospital/clinic licensed health care provider	Hospital/clinic licensed health care provider	Same
Location of implant	Peripheral or thoracic	Peripheral (medial mid arm or upper arm above the elbow or antecubital space and well below the subaxillary area)	Peripheral or thoracic	Thoracic	Peripheral (upper arm) or Thoracic	Same The PeriPort, GrantAdler Rhapsody and Port-A-Cath have a recommended peripheral implantation site (upper arm); the same as the Invisiport.
Design	Septum/port with integrated catheter	Septum/port with an attachable	Septum/port with an attachable	Septum/port with an attachable	Septum/port with an attachable	As a convenience to the user, the catheter is integrated with the port

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		catheter	catheter	catheter	catheter	reservoir.
Catheter Length	53.3 cm	76 cm	Up to 52 cm	Up to 45 cm	76 cm	Within the range of the predicates.
Catheter ID	1.3 mm	1.0 mm	2 mm	Unknown	1.0 mm	Within the range of the predicates.
Catheter OD	2.0 mm	1.7 mm	2.33 mm (7 Fr)	2.7 mm (8 Fr)	1.9 mm	Within the range of the predicates.

5.4 Performance tests to demonstrate substantial equivalency:

To establish the technical equivalency of the Invisiport tests were conducted according to methods presented in FDA Guidance: Guidance on 510(k) Submissions for Implanted Infusion Ports, October 1990, Submission and Review of Sterility Information in Premarket Notification 510(k) Submissions for Devices Labeled as Sterile, December 12, 2008 and provided by FDA in review and discussion. The device passed all testing.

5.5 Conclusion

The Invisiport™ met all established acceptance criteria for performance testing. The intended use and technology of the Invisiport are equivalent to the predicate devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stealth Therapeutics, Incorporated
C/O Mr. Gary J. Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

OCT 13 2011

Re: K110407
Trade/Device Name: Invisiport™
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: October 6, 2011
Received: October 7, 2011

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110407

Device Name: Invisiport™

Indications for Use:

The Invisiport™ is indicated for any patient requiring repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, or the sampling of blood, or for power injection of contrast media when used with a power-injectable Huber needle or infusion set.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

RLJ C. Chan 10/14/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110407